REMARKS

Claims 21-23 are pending in this continuation application. No claims have been cancelled. New claim 24 has been added. Claim 21 has been amended. Accordingly, claims 21-24 are submitted for further prosecution.

Claim 21 has been amended, as set forth above, to describe a method of administering folic acid that reduces the risk of neural tube defects in subjects who are taking oral contraceptives. Support for these amendments is found in the specification at, for example, page 3, lines 5-30 and page 10, line 6 to page 11, line 12.

Claims 21-23 have been rejected under 35 U.S.C § 112, first paragraph, as being non-enabled by the specification. It is the Examiner's view that the specification does not reasonably provide enablement for preventing pregnancy. Applicants respectfully point out that the invention is not directed to preventing pregnancy *per se* but to reducing the risks of disorders that afflict women who accidentally become pregnant while taking oral contraceptives. Women who are taking oral contraceptives do not intend to become pregnant and do not believe that they will become pregnant while taking these contraceptives. Accordingly, many women taking oral contraceptives are not careful about maintaining levels of folic acid adequate to prevent disorders such as spina bifida and anecephaly that can arise from deficiencies in folic acid. As noted in the specification at page 2, lines 10-17, the minimum daily requirement for folic acid is about 50 μg /day, and this requirement increases 3 to 6 times during pregnancy. The US recommended daily allowance for pregnant women is 400 μg/day.

Unfortunately, a number of women accidentally do become pregnant while taking oral contraceptives, primarily due to a lack of compliance. Because women who are taking oral contraceptives can accidentally become pregnant, women on the pill are at increased risk of certain disorders that result from a deficiency of folic acid. That is why, as pointed out in the specification at page 3, lines 5-16, a public health service recommendation was issued advising that all women who can become pregnant should consume 400 μg/day of folic acid to reduce the risk of birth defects (MMWR Morb Mortal Wkly Rep 1992; 41 (RR-14: 1-7). Lower than adequate levels of folic acid in women who accidentally become pregnant while on oral contraceptives cannot easily be corrected. Correction can take at least two months in pregnant women and reserves can last as little as a few weeks.

The objective of the claimed invention is to provide a method of administering folic acid which insures that women who are on the pill and who are at increased risk of birth defects should they accidentally become pregnant while on the pill will have a level of folic acid sufficient to reduce the risk of these defects. This is accomplished by administering a pharmaceutical composition which combines an oral contraceptive and folic acid in a sufficient amount so that as the composition is taken daily, adequate levels of folic acid will be present should a women accidentally become pregnant while taking the oral contraceptive.

Claims 21-23 have been rejected under 35 U.S.C. § 103(a) as being upatentable over Schubring in view of Bamji et al., US Patent No. 5,254,572 (Serfontain), Bielenberg, Harper et al., Check and Drug, Facts and Comparisons (1994). Applicants submit that these references, taken either alone or in combination, fail to teach or even suggest the claimed invention.

Schubring (complete translation included in the IDS being filed herewith) provides an overview of contraceptive products and their use. Schubring lists in Table 5 a number of contraceptive products commercially available in Germany. Some of these products include vitamins and/or minerals in the hormone-free tablets typically included in a contraceptive pill pack. One of the listed products, Norlest 28 Fe, includes seven hormone-free tables that include iron, pyridoxine and folic acid. This reference does not teach daily administration of folic acid by combining folic acid with contraceptive hormones in a single dosage form. If fact, this reference teaches away from the claimed invention, insomuch as Table 5 of Schubrng also lists Norlest 21 which does not include any hormone free tablets and, therefore, does not include any vitamin or mineral supplementation at all.

Bamji alos suggests that intermittent vitamin supplementation can be achieved by including vitamins in the non-hormone tablets in each contraceptive pill package. The reference does not teach or suggest daily administration of folic acid by combining folic acid with an oral contraceptive in the same dosage unit. Thus, Bamji fails to provide a method of administering folic acid that provides an adequate level of folic acid for those women who accidentally become pregnant while taking oral contraceptives. The '572 patent likewise fails to teach or suggest a method for the chronic, daily administration of folic acid. The '572 patent is concerned with administration of B6 vitamins and suggests that these vitamins can be included in oral contraceptive tables. The reference shows no appreciation of the risks of cervical dysplasia and cervical carcinoma for women who accidentally become

pregnant while taking oral contraceptives, or the present method of reducing those risks by combining folic acid and oral contraceptives to provide for chronic, daily folic acid administration.

The Examiner cites Bielberg as disclosing that oral contraceptives can induce folic acid and vitamin B deficiency. Harper et al. is cited for the teaching that folate depletion is a risk factor for cervical dysplasia, and Check is cited for disclosing that folic acid supplementation may help reduce the risk of cervical cancer in women taking oral contraceptives. Finally, Drug Facts and Comparisons is cited for disclosing that the folic acid recommended daily allowance for adults is 400 micrograms.

There is nothing in the combination of seven references relied on by the Examiner that would motivate the skilled person to provide the claimed method of administering folic acid to insure that women who accidentally become pregnant while taking oral contraceptives have adequate stores to prevent neural tube defects such as spina bifida and anecephaly. This motivation is provided only by applicants' own teachings. Such hindsight reconstruction of the invention is clearly impermissible.

In view of the foregoing, applicants submit that the claims are in condition for allowance and favorable action is requested at the earliest possible date.

Applicants do not believe that any fees are required in connection with the filing of this response. Should any fees be required, please charge Deposit Account No. 10-0750/ORT-1316/JSK.

Should the Examiner have any questions regarding this Response, please contact the undersigned attorney at the telephone number listed.

Respectfully submitted,

By: /Joseph S. Kentoffio/
Joseph S. Kentoffio
Reg. No. 33,189

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-3711
Dated: May 1, 2006